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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No. : 09/972,916 Confirmation No.: 4645  
Applicant : Peter M. THULÉ, M.D.  
Filed : October 10, 2001  
Title : GLUCOSE SENSITIVE REGULATOR OF INSULIN  
TRANSCRIPTION  
Group Art Unit : 1635  
Examiner : ANGELL, Jon E.  
Atty. Docket No. : US 1292/01(VA)  
Date : March 14, 2006

**RESPONSE TO REQUEST FOR INFORMATION UNDER 37 CFR 1.105**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Responsive to the Request for Information 37 CFR 1.105 of September 15, 2005, the period for filing a response to which having been extended by four months, from November 15, 2005 to March 15, 2006, by virtue of concurrent filing of a Petition for Extension of Time and the requisite fee, attached hereto are copies of the following information involving the (GIRE)<sub>3</sub>BP-1 Promoter:



1. "A Model of Insulin Gene Therapy", Emory University, Medical Grand Rounds, April 14, 1998.

Description: Oral presentation to weekly conference open and advertised to Emory University students and faculty.

Materials: PowerPoint file: Emory Grand Rounds 21April98 (48 printed slides).

Diapositive slides used for the presentation labeled "Emory Grand Rounds Extra's slides 4/98".

2. Thulé PM, Liu J. Regulated production of insulin from hepatocytes in primary culture. Diabetes 47 (Suppl 1), American Diabetes Assoc., 58<sup>th</sup> Annual Meeting, June 13-16, 1998.

Description: Ten minute oral presentation using slides projected in conference room at scientific meeting. No handouts or written material provided. Written abstract published as above (copy enclosed).



Materials: Word file: ADA LSPdone 2Jan98 (1 page).

PowerPoint file: ADA Talk June 98 (30 printed slides).

Diapositive slides used for the presentation labeled "ADA  
Talk June 98".

3. Thulé, PM, Liu J. Glucose-regulated human insulin production from hepatocytes in STZ-treated rats: a model of insulin gene therapy. Diabetes 48 (Suppl 1), American Diabetes Assoc., 59<sup>th</sup> Annual Meeting, June 19-22, 1999.

Description: Ten minute oral presentation using slides projected in conference room at scientific meeting. No handouts or written material provided. Written abstract published as above (copy enclosed).

Materials: Word file: ADA Abstract June 1999 (1 page).

PowerPoint file: ADA June99 6June (17 printed slides).

Diapositive slides used for the presentation labeled "ADA  
oral abstract June 99".



4. Thulé, PM, Liu J. Glucose regulated hepatic production of human insulin ameliorates hyperglycemia in streptozotocin treated rats. American Society of Gene Therapy, 2<sup>nd</sup> Annual Meeting, June 9-13, 1999.

Description: Ten minute oral presentation using slides projected in conference room at scientific meeting. No handouts or written material provided. Written abstract published as above (copy enclosed).

Materials: Word file: Abstract 1Mar99a (1 page).

Press Release "VA RESEARCHERS DEVELOP POTENTIAL GENE THERAPY FOR DIABETES", June 13, 1999 (2 pages).

PowerPoint file: Gene Therapy Abs. Jun99 25 May (24 printed slides).

Diapositive slides used for the presentation labeled " ASGT 1999".

5. "Progress Toward Insulin Gene Therapy", Georgia Diabetes Research Consortium, Atlanta, GA, September 22, 1999.

Description: Oral presentation to scientific conference of Georgia Investigators. No written or printed material distributed.

Materials: PowerPoint file: GA Diabetes Consortium 23Sep 99 (50 printed slides).



Diapositive slides used for the presentation labeled "GA Research Consortium 9/22/99".

6. "Gene Therapy into the Future", Columbus General Hospital, Medical Grand Rounds, Columbus Georgia, May 16, 2000.  
Description: Oral presentation to Faculty and house staff of Columbus General Hospital in the scope of Emory faculty responsibilities. No written or printed material distributed.

Materials: Word file: Day at Columbus (1 page letter).

PowerPoint file: Columbus Grand Rounds 16May 2000 (82 printed slides).

Diapositive slides used for the presentation.

7. Thulé, PM, Liu J. Expression-level dependent human proinsulin processing by furin in primary hepatocytes. Molecular Therapy 1(5), supp. 1, April/May 2000 (Abstract No. 816 - 1 page).



Description: Poster presentation on June 3, 2000, in conference room at scientific meeting. No handouts or written material other than poster provided. Written abstract published as above (copy enclosed). No written or printed material distributed.

Materials: Word file: Poster29May ASGT June2000 (13 pages).

PowerPoint files: Figs ASGT Poster & figure1 (4 printed slides).

Actual poster presented at meeting.

8. "Advances in Insulin Gene Therapy", Crawford W. Long Hospital, Atlanta, GA, Medical Grand Rounds, March 30, 2001.

Description: Oral presentation to Emory University faculty and house staff stationed at Crawford W. Long Hospital, Atlanta, GA. within the scope of Emory faculty responsibilities. No written or printed material distributed.

Materials: Powerpoint file: CWL Grand Rounds Fri 30Mar01 (67 printed slides).

Note: presentation was performed using a digital projector from this file.



9. Thulé PM, Martin, SA, Olson, DE, Porter, MH. 2001 Glucose and insulin responsive hepatic insulin gene therapy in spontaneously diabetic BB Wor rats. Molecular Therapy 3(5), 2/2, S94, May 2001 (Abstract No. 268 - 1 page).

Description: Poster presentation on May 30 - June 3, 2001, in conference room at scientific meeting. No handouts or written material other than poster provided. Written abstract published as above (copy enclosed).

Materials: Word file: ThulePoster ASGT Figs Jun01 (14 pages).

Actual poster presented at meeting.

10. Porter, MH, Martin, SA, Olson, DE, Thulé PM. Intrahepatic insulin production modifies intermediary carbohydrate metabolism in primary cultured hepatocytes. Molecular Therapy 3(5), 2/2, S232, May 2001 (Abstract No. 661 - 1 page).

Description: Poster presentation on May 30 - June 3, 2001, in conference room at scientific meeting. No handouts or written material other than poster provided. Written abstract published as above (copy enclosed).



Materials: Word files: Porter Martin Olson Thule (1 page) (text of abstract).

ASGTPorter with Figs Jun 01 (10 pages - File is incomplete. Inventor cannot readily obtain a more complete file.) has been replaced with ASGT Porter, Paveglio, Olson & Thule 22 May (10 pages): this file was used to create the poster.

Actual poster presented at meeting.

11. Kozlowski M, Rubin J, Thulé PM. Delivery of regulatable insulin secretion system via AAV into hepatocytes *in vitro*. Molecular Therapy 3(5), 2/2, S396, May 2001 (Abstract No. 1129 - 2 pages).

Description: Poster presentation on May 30 - June 3, 2001, in conference room at scientific meeting. No handouts or written material other than poster provided. Written abstract published as above (copy enclosed).

Materials: Word files: Kozlowski Rubin Thule01 (abstract text - 1 page).

Kozlowski 22 May 01 (12 pages) (poster was made from this file).

PowerPoint file: Fig1-7pic1 (7 printed slides).

Actual poster presented at meeting.



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12. "Hepatic Insulin Gene Therapy", Annual Meeting, Richmond, VA  
Chapter, Juvenile Diabetes Research Foundation, June 16, 2001.

Description: Oral presentation to lay supporters of Juvenile Diabetes Research Foundation International. No written or printed material distributed.

Materials: Powerpoint file: JDRF19Jun01 (61 printed slides).

Note: presentation was performed using a digital projector  
from this file.

A completed Form 1449B/PTO listing the above-noted references thereon is enclosed herewith. The Examiner is respectfully requested to return an initialed copy of Form 1449B/PTO along with the next communication in connection with this case.



Appl. No. 09/972,916

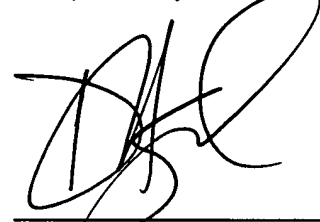
Response to Request for Information Under 37 CFR 1.105 dated March 14, 2006

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It is believed that no fee is due for this submission. Should that determination be incorrect, however, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully Submitted,

A handwritten signature in black ink, appearing to be 'D. Agarwal', written over a horizontal line.

DINESH AGARWAL  
Attorney for Applicant(s)  
Reg. No. 31,809

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PTO/SB/08B (6-95)

Approved for use through 07/31/96, OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

1449B/PTO  
Rev. 10/95U.S. Department of Commerce  
Patent and Trademark Office

## Complete if Known

LIST OF PRIOR ART CITED BY  
APPLICANT  
(use as many sheets as necessary)

MAR 14 2006

Sheet

1

of

2

Application Number	09/972,916
Filing Date	October 10, 2001
First Named Inventor	Peter M. THULÉ, M.D.
Group Art Unit	1635
Examiner Name	ANGELL, Jon E.
Attorney Docket Number	US 1292/01 (VA)

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book), magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, country, where published, source.	T <sup>2</sup>
		1. "A Model of Insulin Gene Therapy", Emory University, Medical Grand Rounds, April 14, 1998. PowerPoint file: Emory Grand Rounds 21April 98 (48 printed slides).	
		2. Thulé PM, Liu J. Regulated production of insulin from hepatocytes in primary culture. Diabetes 47 (Suppl 1), American Diabetes Assoc., 58 <sup>th</sup> Annual Meeting, June 13-16, 1998. Word file: ADA LSPdone 2Jan 98 (1 page). PowerPoint file: ADA Talk June 98 (30 printed slides).	
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Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



